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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ARIA DIAGNOSTICS, INC., Plaintiff, v. SEQUENOM, INC., Defendant/ Counterclaim-Plaintiff, v. ARIA DIAGNOSTICS, INC., Counterclaim-Defendant, and ISIS INNOVATION LIMITED, Nominal Counterclaim-Defendant.	Case No. 3:11–cv–06391-SI **DECLARATION OF WILLIAM WELCH IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION** Date: April 13, 2012 Time: 9:00 a.m. Place: Courtroom 10, 19th Floor

I, William Welch, declare:

1. I am Senior Vice President of Diagnostics at Sequenom, Inc. ("Sequenom"). I have personal knowledge of the facts stated in this declaration and, if called as a witness, I could and would testify competently thereto. This declaration is made in support of Sequenom's Motion for Preliminary Injunction filed concurrently herewith.

I. PERSONAL BACKGROUND AND EDUCATION

2. I have been employed at Sequenom since January 11, 2011, when I was appointed to the position of Senior Vice President of Diagnostics. My role and responsibilities in this position are to oversee and manage all aspects of Sequenom's molecular diagnostics business. I report directly to Sequenom's Chief Executive Officer, Harry F. Hixson, Jr.

3. Prior to joining Sequenom, I had over 18 years of leadership experience in medical devices and biotechnology companies. Most recently before joining Sequenom, I was a managing director at SkyDeck Associates LLC where I served as a consultant to molecular diagnostic companies in the personalized medicine sector. From August 2005 to September 2009, I was senior vice president and chief commercial officer at Monogram Biosciences, where I led sales, marketing, commercial operations, and alliances with pharmaceutical companies for its oncology and virology businesses. At Monogram, I had a direct role in the commercial launch of the first molecular assay in the personalized medicine sector, an assay linked to an HIV therapeutic drug, and the commercial launch of Monogram's first oncology test for breast cancer. Prior to Monogram, from 2001 to 2005, I was vice president of sales and marketing at La Jolla Pharmaceuticals, and, from 1999 to 2001, vice president of global marketing at Dade Behring MicroScan. I entered the healthcare industry in 1993 with Abbott Laboratories where for the next six years I held positions of increasing responsibility including general management.

4. I received a B.S. in Chemical Engineering with Honors from the University of California, Berkeley in 1983, and an M.B.A. from Harvard University Business School in 1988.

II. SEQUENOM

5. Sequenom is a molecular diagnostics and genetic analysis company. Sequenom is committed to providing molecular diagnostic testing services, and our primary focus is and for the past several years has been to commercialize non-invasive prenatal diagnostics testing services. In the genetic analysis side of its business, Sequenom provides research use-only products, services, applications, and genetic analysis products that translate the results of genomic science into solutions for biomedical research, translational research, molecular medicine applications, and agricultural, livestock, and other areas of research.

6. Sequenom was founded in 1994. We are headquartered in San Diego, California. Sequenom's wholly-owned subsidiary, Sequenom Center for Molecular Medicine, LLC ("Sequenom CMM"), currently operates a laboratory located in Grand Rapids, Michigan, and a second laboratory in San Diego, California. Both laboratories are accredited by the College of American Pathologists ("CAP") and compliant with the certification requirements for high complexity testing under the Clinical Laboratory Improvement Amendments of 1988, as amended ("CLIA"). Sequenom CMM develops and validates what are known as laboratory developed tests for use in and solely by Sequenom CMM as a testing service to physicians.

III. SEQUENOM'S MOLECULAR DIAGNOSTICS BUSINESS

7. Sequenom is, and for the last several years has been, primarily focused on developing and commercializing a non-invasive prenatal diagnostic test to identify pregnancies at risk for Down syndrome and other fetal aneuploidies. An aneuploidy is a type of chromosome abnormality and is a common cause of genetic disorders such as trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), and trisomy 13 (Patau syndrome). It is my understanding that these three chromosome disorders make up the most common aneuploidic conditions in the United States today.

8. Through its wholly-owned subsidiary, Sequenom CMM, Sequenom began offering on a commercial basis a laboratory developed test, or LDT, for fetal aneuploidies in mid-October 2011. Sequenom initially marketed this LDT under the brand name MaterniT21 for use to detect trisomy 21, Down syndrome. Based on a further validation study, Sequenom CMM expanded the

application of the MaterniT21 LDT to include the detection of trisomies 18 and 13 in addition to trisomy 21, as was publicly announced by Sequenom CMM on February 8, 2012. The LDT remained the same, but was rebranded under the name MaterniT21 PLUS to denote the expanded application of the LDT (hereinafter "the MaterniT21 test").

9. With the launch of the MaterniT21 test, Sequenom was the first company to bring a non-invasive prenatal diagnostic test for Down syndrome (or any other fetal aneuploidy) to market. The MaterniT21 test is Sequenom's "flagship" – *i.e.*, Sequenom believes that the MaterniT21 test will allow Sequenom to establish itself as the leader in the new market of non-invasive prenatal diagnostic tests for fetal aneuploidies.[1]

10. Sequenom's technology is a revolutionary approach to prenatal genetic testing. The MaterniT21 test is a non-invasive alternative to conventional prenatal diagnostic procedures that use invasive means, such as amniocentesis and chorionic villus sampling ("CVS"). Invasive methods such as amniocentesis and CVS involve probes or needles being inserted into the uterus of a pregnant woman to obtain fluid or tissue samples from the placenta or fetus. These invasive procedures impose significant risks to both the fetus and the mother, including the risk of miscarriage.

11. By contrast, Sequenom's non-invasive technology uses a simple maternal blood draw, and poses no significant risk to the fetus or mother. Rather than harvesting placental tissue cells (as is required for CVS), or entering the uterus to sample the amniotic fluid surrounding the fetus (as is done with genetic amniocentesis), Sequenom's patent-protected technology extracts and analyzes DNA material directly from a maternal blood sample. By bringing the MaterniT21

[1] In addition to the MaterniT21 test, Sequenom CMM has validated and currently offers to physicians three other LDTs: SensiGene RHD Genotyping to determine a mother's blood type and RhD factor; SensiGene Cystic Fibrosis Carrier Screening to help identify individuals who may have an increased risk of having certain CF genetic mutations; and RetnaGene AMD to predict genetic predisposition to develop late-stage (wet) age-related macular degeneration. Prior to our commercial launch of MaterniT21 in October 2011, we commercially launched a testing service for cystic fibrosis carrier screening in September 2009, a testing service for non-invasive prenatal Rhesus D in early 2010, and a testing service for assessment of risk for developing wet AMD in the second quarter of 2011.

test to market, Sequenom is serving a previously an unmet clinical need: a safer way for doctors and women to assess the risk of a pregnancy carrying a fetal aneuploidy. Ultimately, the MaterniT21 test has the potential to supplant invasive diagnostics such as amniocentesis or CVS, as it provides a much safer alternative.

12. The MaterniT21 test analyzes circulating cell-free fetal nucleic acid extracted from a maternal blood sample. Patient samples are collected by physicians and submitted to Sequenom CMM for testing. The maternal blood samples are processed at Sequenom CMM's CAP-accredited and CLIA-certified laboratory, where the MaterniT21 test was developed and validated. The results are reported back to the ordering physician. The turnaround time of 8 to 10 days for the MaterniT21 test is similar to the turnaround time for amniocentesis or CVS.

13. The MaterniT21 test is indicated for use in pregnant women who are at increased risk (by medical and clinical indicators) of carrying a fetus with Down syndrome or trisomies 18 or 13, including women who will be over age 35 at term, have a suspicion of problematic pregnancy indicated by a positive serum screening result, a positive ultrasound result or prior affected pregnancy or family history. In the United States, there are an estimated 750,000 such high-risk pregnancies each year.[2]

14. The purpose of the MaterniT21 test is to provide physicians and their patients with critical new information to help them make better informed decisions about the patients' healthcare and pregnancies. When the test results are obtained by the physician, he or she will consult with the patient and, if the test is positive, the physician and patient will determine how this data is used. At least initially, the likely outcome from a positive test is that the doctor will recommend that a CVS or amniocentesis be performed to confirm the test. Conversely, if the test is negative, as it will be in most cases, Sequenom believes that with the high sensitivity and specificity of its MaterniT21 test, the physician and patient may decide that the information is

[2] Sequenom has initially focused on the high risk group because our clinical data is derived from clinical studies of women in the high risk group. Sequenom intends to expand the test's coverage to include the lower risk group if and when supported by clinical data from further studies.

sufficient for them to make a risk assessment of what they wish to do, and potentially no further tests are required.

IV. SEQUENOM IS CREATING THE MARKET FOR NON-INVASIVE PRENATAL TESTING FOR FETAL ANEUPLOIDIES

15. Sequenom is a pioneer in bringing non-invasive prenatal testing to market, and the first company to market a non-invasive prenatal diagnostic test for fetal aneuploidies. Sequenom commercially launched the MateriT21 test on October 17, 2011. A true and correct copy of Sequenom's press release announcing the launch of the MateriT21 test is attached to this declaration as Exhibit 1.

16. The market for the MateriT21 test initially is driven by acceptance of its clinical utility by Maternal Fetal Medicine (MFM) Specialists, also referred to as Perinatologists, and Obstetricians (OB/GYNs) practicing at high volume birthing centers. Genetic Counselors also play a role as resources to physicians for counseling patients on genetic markers and pregnancy consequences. Ultimately, patients are the end-users of the testing service, and as they become aware of the availability of the test, they may go into physicians' offices requesting the test.

17. At launch, Sequenom began offering the test to physicians in 20 major metropolitan regions across the United States. Sequenom initially targeted approximately 3,000 MFM specialists and about 2,000 OB/GYNs in these regions, each with high volume practices.

18. The early traction of the MateriT21 test has been very encouraging. Sequenom did not premarket the MateriT21 test before launch as the data was blinded to the company by Women & Infants Hospital, which participated in a pivotal validation study of the test. From this cold launch in mid-October 2011 through year-end 2011, Sequenom CMM performed about 1,000 MateriT21 tests, which equates to about 80 tests per week. The test run-rate accelerated at the end of 2011 to a pace of 9,000 tests per year (about 170 tests per week). These results are especially encouraging considering that the MateriT21 test was launched during the holiday season and, before mid-December 2011, the maternal blood samples had to be collected at a processing site outside the physician's office and shipped on dry ice. By year-end 2011, Sequenom introduced a new blood draw tube for the collection of MateriT21 test samples, allowing for blood

to be drawn directly at a physician's office and shipped directly to Sequenom CMM at ambient temperature.

19. Early adopters of the groundbreaking MaterniT21 test have provided positive feedback to Sequenom, including statements by maternal-fetal MFM specialists that Sequenom featured in a press release on December 19, 2011, a true and correct copy of which is attached hereto as Exhibit 2. For instance, Dr. Barbara O'Brien, MFM specialist and director of Perinatal Genetics at Women's & Infants Hospital – which participated in the validation study of the MaterniT21 test: stated that "the test has an important place in the plan of care for women who are at a high risk for carrying a child with Down syndrome." *See id.* Dr. Frank Boehm, Vice Chairman of the Department of Obstetrics and Gynecology and Director of MFM at Vanderbilt Center for Women's Health, stated: "As part of our mission to provide the best possible medical care to patients visiting our facility, we are pleased to provide patients with access to Sequenom CMM's MaterniT21 LDT as an opportunity to gain valuable information early in a woman's pregnancy." *Id.*

20. Sequenom has actively progressed the rollout of the MaterniT21 test since its launch four months ago. The MaterniT21 test is now (and has been since early January 2012) available in all 50 states in the United States, and Sequenom is now targeting a total of 7,500 physicians (including MFM specialists and OB/GYNs) with high volume practices. Sequenom estimates that this represents substantially all of the accessible market.

21. Sequenom has been and is directing substantial resources to marketing and sales of the MaterniT21 test. As of early January 2012, Sequenom has doubled its sales force personnel, increasing from 22 active field sales representatives at initial launch of the MaterniT21 test to more than 44 active field sales representatives. Sequenom plans to expand to 80 active field sales representatives as and when appropriate to accommodate market expansion. These field sales representatives require extensive training, as they must be prepared to educate physicians and other healthcare providers, as well as third-party payors, regarding the clinical benefits and cost effectiveness of the MaterniT21 test.

22. Sequenom has established a corporate goal of billing at least 25,000 MaterniT21 tests in 2012. Sequenom hopes to substantially exceed this internal goal, and the early results are promising. Since the initial launch of the MaterniT21 test, every week has been a growth week in terms of sales volume. As Sequenom has publicly stated, an optimistic high case for sales of the MaterniT21 test in 2012 is approximately 60,000 tests.

23. Some market analysts predict lower test volumes and others predict higher volumes than Sequenom's stated internal goal of billing at least 25,000 MaterniT21 tests. Because the market is new and untested, the analysts often revise their own projections. For instance, Auriga USA, LLC, an equity research firm, in its analyst report dated January 30, 2012 stated (referring to Sequenom by its stock symbol SQNM): "We believe SQNM's marketing message is resonating with both physicians and patients, and bodes well for a solid launch." In this same report, Auriga also stated: "We had been extremely conservative in our projections (10,000) due to the novel nature of the test. However, we believe that an early, highly sensitive, non-invasive option for high risk pregnancies may expand the addressable market. We now expect SQMN will bill 45,000 tests in 2012." A true and correct copy of this Auriga report is attached to this declaration as Exhibit 3.

24. Auriga underscored that this is a brand new market, stating in its January 30, 2012 report: "Given the newness of the test and associated learning curve, we believe the uptake will accelerate through the year. Our new 45,000 test estimate assumes SQNM can penetrate ~ 10% of 5,000 physicians (say key opinion leaders, early adopters and large regional practices), each doing 90-100 tests per year. Given the feedback from early adopters (suggesting 500-600 per year) we believe our numbers are achievable." *See id.*

25. Another equity analyst, Dougherty & Company, in its report dated February 3, 2012, upwardly adjusted its projections of Sequenom's volume of MaterniT21 tests in 2012 to 27,600 tests, stating that it is "adjusting [its] year-1 unit volume assumptions higher (new est. 27.6K units; old est. 20.3k units; mgmt. guidance 25k units) . . . ." A true and correct copy of this analyst report is attached to this declaration as Exhibit 4. Another investment and equity research firm, Oppenheimer, in its report dated January 12, 2012, estimated that Sequenom will bill

approximately 8,500 MaterniT12 tests in 2012, which is at the low end of analyst estimates. A true and correct copy of Oppenheimer's report is attached to this declaration as Exhibit 5.

26. Sequenom's investor relations department tracks analysts' views and has reported to me that the consensus view (*i.e.*, the average estimate) among eleven different analysts has Sequenom selling 22,135 MaterniT21 tests in 2012. Sequenom's laboratory in San Diego currently has the sequencing capacity to manage approximately 100,000 patient samples on an annual basis, which exceeds even the highest estimates of market demand in 2012. Sequenom CMM is increasing its sequencing capacity in its San Diego laboratory. It also is building out a new CLIA laboratory in North Carolina, which Sequenom expects to be operational in the second half of 2012 and to create 242 new jobs. The Governor of North Carolina announced the state's agreement with Sequenom on this new laboratory in a press release on October 12, 2011, a true and correct copy of which is attached to this declaration as Exhibit 6. With the San Diego laboratory, and its expanding capacity, and the soon-to-be operational laboratory in North Carolina, Sequenom currently has the capacity to fully serve 100% of patient and physician demand for non-invasive tests for fetal aneuploidies for 2012, 2013, and the foreseeable future.

V. PRICING STRUCTURE/INSURANCE REIMBURSEMENT

27. There are different types of commercial payors, including insurance companies providing traditional indemnity (or "fee-for-service") plans and managed care organizations such as Health Maintenance Organizations (HMOs) and Preferred Provider Organizations (PPOs). The majority of Americans with private health insurance are enrolled in some type of managed care plan: either an HMO or PPO or, less commonly, point-of-service (POS) plans that combine the features of an HMO and a PPO. There are numerous commercial payors, the top six (by covered lives) are Wellpoint, United Health Group, Aetna, Blue Cross/Blue Shield, CIGNA, and Health Care Service Corporation.

28. Managed care plans contract with doctors, hospitals, clinics, and other health care providers such as pharmacies, labs, x-ray centers, and medical equipment vendors. This group of contracted health care providers for a particular plan is often referred to as that plan's "network." Some managed care plans (such as HMOs) have a "closed" system that provides reimbursement

coverage only for services from a network provider, except for certain types of care that may not be available from a network provider. Other managed care plans (such as PPOs) have an "open" system in which plan members can seek services both in and outside of the health plan, but typically a plan member will pay a higher copayment (or "copay") for out-of-network services.

29. The various insurance companies, HMOs and PPOs each have their own policies and practices with respect to the level of health care cost reimbursement they provide. This is especially the case with reimbursement for services provided "out-of-network." With a new and innovative service like the MaterniT21 test, the reimbursement level is a matter of negotiation. Sequenom will not know what the reimbursement level will be until policies are adopted by insurance payors and Sequenom enters into contracts with payors. This is a similar process that other unique, highly complex diagnostic tests had to go through when they entered the market.

30. Sequenom is initially offering the MaterniT21 test on an out-of-network basis while actively negotiating with major insurance coverage providers to ensure eligible patients will have coverage for this important new diagnostic test. Sequenom has implemented a patient-friendly billing policy for the MaterniT21 test, with the cost to insured patients to be no more than $235 out-of-pocket expense. Until contracts with insurance payors are in place, Sequenom bills the payors directly, billing at the list price, and pursues reimbursement on a case-by-case basis. Currently, Sequenom's list price for the MaterniT21 test is $2,762. The insurance payor may pay the list price or, more typically, a portion of the billed amount. Sequenom then pursues the insurance payor for any outstanding amount, through a negotiation or appeal process, with the expectation of receiving additional reimbursement. This series of billing and negotiation may take up to nine months. It is Sequenom's policy that it does not and will not bill patients for the outstanding billed amount after negotiations with the payor.

31. The negotiation with an insurance payor involves working to persuade that payor that the test is medically necessary and that the price is justified, based on qualitative and quantitative health economic factors. The qualitative factors include such things as the MaterniT21 test is highly accurate and non-invasive which provides valuable information to the mother with no risk to her or the fetus, thereby avoiding the very high maternal anxiety levels

related to invasive procedures such as amniocentesis and CVS. The quantitative factors include economic and market justifications for the test's price, such as the research and development costs, the costs of goods sold, competitive and/or avoided medical procedures, and patient/physician demand for the test.

32. With technology as pioneering and innovative as the MaterniT21 test, and with an adoption rate that nobody can precisely predict, this is a very dynamic environment. At present, the reimbursement rates, payment timing, interest in contracting, and sensitivity to patient demands vary significantly among the insurance payors. Sequenom will not know what the minimum expected reimbursement will be until we work through the issues with the insurance payors and gain experience with this new market. In my experience with other unique diagnostic tests, the learning and negotiation process for establishing reimbursement rates for the MaterniT21 test can be expected to take a minimum of one year and more likely two or more years.

33. Because the MaterniT21 test is new and groundbreaking, it does not fit within any of the existing codes in the Current Procedural Terminology (CPT) code set maintained by the American Medical Association through its CPT Editorial Panel. The CPT code set describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payors for administrative, financial, and analytical purposes. Sequenom currently bills the MaterniT21 test under a "miscellaneous" CPT code, which is used for procedures, devices, and services that have not been assigned a unique CPT code.

34. HMOs typically do not provide reimbursement for services provided out-of-network. For HMO participants who want the MaterniT21 testing, Sequenom will provide the requested testing if the HMO has pre-authorized the reimbursement amount. Again, this requires negotiation on a case-by-case basis. For insured patients choosing to pay entirely out-of-pocket (and for uninsured patients), the MaterniT21 test price is approximately $1,933. Additionally, Sequenom has a patient assistance policy for patients who are not insured and do not have

sufficient funds for payment. At launch, Sequenom established 50 free tests per quarter for qualifying patients.

35. The process for establishing reimbursement from Medicaid involves another set of players and considerations. Medicaid is the United States health program for families with very limited income, which is jointly funded by the state and federal governments. Currently, all fifty states participate in Medicaid, with each state implementing its own Medicaid program (*e.g.*, California's Medi-Cal program). Sequenom expects that negotiation with states over Medicaid reimbursement rates will be a complex process that will take at least one to two years with any particular state.

VI. SEQUENOM'S R&D AND PRODUCT LAUNCH COSTS

36. The MaterniT21 test went through the full FOVV – feasibility, optimization, verification and validation – at Sequenom CMM. Sequenom CMM performed a pilot 96-patient study of a trisomy 21 test using massively parallel shotgun sequencing, and presented the results of this study at a meeting of the American Society of Human Genetics in November 2010. Based on the results of this study, Sequenom CMM started and completed a larger study that analyzed 480 patient samples collected from pregnant women at increased risk for fetal chromosome 21 aneuploidy. A manuscript describing the results from this larger laboratory verification study was published online on February 10, 2011, in the *American Journal of Obstetrics & Gynecology*.

37. Based on the results from these two studies, Sequenom CMM undertook a large pivotal clinical validation study. This study was sponsored and funded by Sequenom, but was designed, implemented, analyzed, and reported by researchers at Women & Infants Hospital and Alpert School of Medicine of Brown University in Rhode Island ("Women's Hospital"). Between April 2009 and February 2011, twenty-seven sites world-wide enrolled women in the multi-center validation study, and patient samples were collected under the auspices of Women's Hospital. In this study, Sequenom CMM tested and analyzed patient samples over a nine-week period (January to March 2011). This clinical validation study was detailed in an article authored by Sequenom's academic collaborators that was published online in the journal *Genetics in*

Medicine on October 17, 2011, coinciding with Sequenom's commercial launch of the MaterniT21test. *See* Exhibit 1.

38. Sequenom's academic collaborators at Women's Hospital recently published the results of another study conducted during the same testing period described in the preceding paragraph. Sequenom announced in a press release issued February 2, 2012, that the study demonstrated that, in addition to trisomy 21 (Down syndrome), the MaterniT21 test can detect fetal trisomies 18 (Edwards syndrome) and 13 (Patau syndrome) with high accuracy from a maternal blood sample. The full results of the study were published in the online version of *Genetics in Medicine*, to which Sequenom's press release provided an Internet link. A true and correct copy of Sequenom's February 2, 2012 press release is attached hereto as Exhibit 7.

39. In addition to its significant investment in these clinical studies, Sequenom has invested substantially in Sequenom CMM's information technology infrastructure to enhance the capabilities of the laboratories to track samples and provide electronic ordering and reporting and have put into place sample collection and transportation logistics that can be scaled as demand for the MaterniT21 test increases.

40. Sequenom also has committed to establish a CLIA laboratory in North Carolina, which Sequenom expects to be operational in the second half of this year 2012. Sequenom has committed to make an $18.7 million investment in an existing research park, with the expectation that this will create 242 jobs. As noted earlier in this declaration, the Governor of North Carolina issued a press release announcing the state's agreement with Sequenom. In this press release, Paul Maier, Chief Financial Officer of Sequenom and President of Sequenom CMM, stated that "Sequenom is rapidly advancing innovative technologies and has been looking at the right venue to expand its capacity, so we're extremely pleased to have reached an agreement with North Carolina." *See* Exhibit 6.

41. Between April 2009 and the launch of the test in October 2011, Sequenom's research and development costs and other pre-launch expenses for the MaterniT21 test were on the order of $70 million.

42. Research and development remains a high priority as Sequenom is pursuing a number of initiatives to further improve the process and the capacity for the MaterniT21 test. For instance, in addition to Sequenom's investment in its LDT for fetal aneuploidies, Sequenom is on a parallel path to commercialize a test that can be used outside the CLIA-laboratory setting, which requires various FDA approvals. Other initiatives and activities include further clinical trials and maintaining and expanding the infrastructure and operational capacity that Sequenom has built up, including sales force and laboratory personnel, information technology infrastructure, sample collection tracking systems, and electronic order and reporting systems. Sequenom estimates that its investment in the ongoing launch of MaterniT21 will exceed $70 million in 2012.

43. A number of analysts covering Sequenom have their own estimates, which they provide to the investment community. For example, William Blair, an equity research firm, in its report dated January 9, 2012, stated that its financial model projects Sequenom "spending nearly $100 million over the next 12 months on the MaterniT21 rollout." A true and correct copy of this analyst report is attached to this declaration as Exhibit 8.

VII. ARIA'S ANNOUNCED PLANS TO ENTER THE MARKET

44. Aria, which was formerly known as Tandem Diagnostics, Inc., is a private company that operates a laboratory in San Jose, California. Aria has been operating in stealth mode until just this past month. Investment bank and equity research firm William Blair stated in its January 16, 2012 report: "Although we have spoken with [Aria's] management before, Aria chose this past week to open up about its test and plans for commercialization." A true and correct copy of this analyst report is attached to this declaration as Exhibit 9.

45. In public statements made at the J.P. Morgan Healthcare Conference in San Francisco in January 2012, Aria stated that it plans to commercially launch its test in the first half of this year. "As far as strategy," William Blair wrote, "Aria has told us consistently it plans to compete on price, throughput advantages, and product positioning, and it confirmed this in its presentation at the J.P. Morgan Healthcare Conference." *See id.* Other analysts have issued similar reports. For instance, in its January 9, 2012 report, Oppenheimer wrote that Aria "hopes

to offer a substantially lower price point (<$1,000), versus SQNM's $2,700 list." A true and correct copy of the Oppenheimer report is attached to this declaration as Exhibit 10.

46. On February 6, 2012, Aria issued a press release announcing that "its new prenatal test has been named the Harmony Prenatal Test™." A true and correct copy of this press release is attached to this declaration as Exhibit 11. In this press release, Aria goes on to state that "[t]he test is a directed non-invasive approach to cell-free DNA (cfDNA) analysis in maternal blood to detect common trisomies linked to genetic disorders." *Id.*

47. At the Society for Maternal-Fetal Medicine (SMFM) conference held on February 6 through 11, 2012, in Dallas, Texas, Aria publicly stated that the list price for its test will be $900. Aria also distributed promotional material at the SMFM conference, including a brochure on its Harmony Prenatal Test. A true and correct copy of the English language version of this brochure is attached hereto as Exhibit 12.

VIII. IMPACT ON SEQUENOM IF ARIA ALLOWED TO LAUNCH ITS INFRINGING PRENATAL TEST

48. It is my understanding that the process for analyzing cell-free fetal nucleic acids to detect fetal aneuploidies is protected by United States Patent No. 6,258,540 (the "'540 patent"). Sequenom has brought the present lawsuit against Aria to enforce Sequenom's exclusive rights under the '540 patent and to halt Aria from offering, selling, and performing other activities in respect to its prenatal test (now called Harmony Prenatal Test), which the lawsuit alleges infringes the '540 patent. It is my understanding that it may take up to two years before there is a trial in this lawsuit and, if not earlier resolved by a motion for summary judgment, this lawsuit may be pending for all of 2012 and 2013 (at least). I further understand that one form of relief in a patent infringement action is a permanent injunction, which would be available only after a trial (or summary judgment) in which a final determination of infringement and validity is made. I further understand that the purpose of a preliminary injunction is to prevent likely infringing activities during the pendency of a lawsuit in cases where such infringing activity will cause irreparable harm to the plaintiff – that is, harm that cannot be fully remedied by an award of damages and permanent injunction. This is such a case. Sequenom will be severely and

irreparably harmed if denied its exclusive market opportunities due to Aria's infringement of the '540 patent while this lawsuit is pending.

49. The MaterniT21 test is Sequenom's flagship offering – it is the most significant and valuable product or service that Sequenom offers. As the investment and equity research firm Oppenheimer put it, "the real value of SQNM lies within the just-launched MaterniT21 test for Trisomy 21." *See* Exhibit 5 at 3. Sequenom's business is substantially dependent on its ability to obtain the full benefit of its exclusive rights to sell a non-invasive fetal aneuploidy test that uses the technology embodied in the '540 patent.

50. Sequenom commercially launched the MaterniT21 test just four months ago (on October 17, 2011) as the very first non-invasive prenatal test for fetal aneuploidies brought to market. The MaterniT21 test is in the early growth phase in the marketplace. In my experience, this phase is generally the time period when a company and its key product distinguishes itself from current practices, gains medical trust, expands its customer base, and establishes a leadership reputation in the market. The company's prospects depend on the MaterniT21 test establishing and maintaining a dominant leadership position in the market for non-invasive prenatal test for fetal aneuploidies.

51. Sequenom seeks to represent to market participants that it is the only company that offers a non-invasive prenatal diagnostic test for fetal aneuploidies, based on Sequenom's patent-protected technology for analysis of circulating cell-free fetal nucleic acid in maternal blood. At this time, Sequenom cannot prevent Aria from promoting its infringing test without a Court order. If Sequenom's patented technology contributes to Aria's market position (instead of exclusively contributing to the market position of Sequenom), then Aria's marketing practices will have a severe negative impact on Sequenom's efforts to market its testing service to physicians and their patients, and to negotiate and establish premium reimbursement rates with the various insurance coverage providers.

52. If Aria is not prevented from offering and selling the accused Harmony Prenatal Test, the resulting harm to Sequenom will include loss of sales and market share precisely at the stage when Sequenom is rolling out the MaterniT21 test. Every lost opportunity to provide and

bill its testing service for a particular pregnancy is a sale that Sequenom has lost forever, and Sequenom will not have another opportunity to sell its testing service to that "consumer" unless she becomes pregnant again. This lost opportunity and time delay for another opportunity, if any, will irreparably harm Sequenom's marketing momentum and the rate of adoption of the MaterniT21 test.

53. Aria's entry into the market will also inevitably and irreversibly erode the price that Sequenom would be able to command for its MaterniT21 test. The price that Sequenom is able to charge for the MaterniT21 test depends most significantly on the reimbursement rates that Sequenom is able to negotiate with insurance coverage providers. Sequenom is in the process of negotiating reimbursement rates with a number of major payors. If Aria is allowed to enter the market, the dynamics of Sequenom's negotiations with these payors will be dramatically altered, as Sequenom will have lost the ability to leverage its exclusivity and the payors will insist upon resetting the negotiations to account for Aria's offering a competing test at a lower price.

54. If Aria enters the market with its stated list price of $900 for the accused test, it will severely undercut the price that Sequenom otherwise would be able to command for the MaterniT21 test. If Aria begins marketing and selling its infringing test at a lower price point than Sequenom, as appears to be Aria's commercial strategy, then the dynamics of Sequenom's negotiation with insurance payors over reimbursement rates will adversely impacted. The insurance payor will not pay more than the retail price in a local market for a particular service. Insurance providers have considerable bargaining power and can insist on "take it or leave it" contracts that result in low reimbursement. Put simply, Sequenom will be forced to accept dramatically lower prices for its testing service to remain price-competitive with Aria's infringing testing service.

55. The price erosion that Sequenom will inevitably sustain if Aria enters the market with its infringing test will in all likelihood be irreversible. Sequenom will not recapture its ability to command premium pricing for the MaterniT21 test after ultimately prevailing in this litigation if Aria is allowed to market its infringing test in the interim period. It has been my experience that, once a reimbursement rate is established for a diagnostic product or service, the

insurance payors will not increase the reimbursement rate significantly, if at all, above the rate that was initially established. The payor will take the position that the reimbursement rate that the product or service provider was willing to accept when the rate was initially established is the rate that reflects the proper economics of the product or service. In view of the payors' asymmetric bargaining power, Sequenom would face an uphill battle in seeking to renegotiate higher reimbursement rates after it ultimately succeeds in this litigation, as the market price will have been set in the eyes of the insurance payors, and it is a virtual certainty that Sequenom will not be able to "unring the bell" and achieve the reimbursement rates it otherwise would be able to command without Aria's infringing test on the market while this litigation is pending.

56. The imperative to prevent Aria from entering its infringing test on the market is heightened further by the relatively limited period of time that Sequenom has to enjoy and take full advantage of its exclusive rights under the '540 patent. The '540 patent and its concomitant monopoly rights expire in 2017, just five years from now. Sequenom's exclusive, monopoly rights under the '540 patent expire with the patent. Moreover, technology is moving quickly in the field of prenatal diagnostics, and there is the potential for new technologies to emerge that may make the MaterniT21 test obsolete. Sequenom is not aware of any such technology at present, but the potential is not merely imaginary. For instance, investment bank and equity research firm William Blair, in its January 16, 2012 report, stated that it spoke with management of Cellscape Corporation, a private company in California, regarding "its planned prenatal diagnostic" test and that Cellscape "is pursuing a unique approach that has the possibility of being a game changer in the space; however, it is still very early in its progress." *See* Exhibit 9 at 2. In view of the relatively fast-moving technology in this field, Sequenom will be irreparably harmed unless it is afforded the full measure of its exclusive rights to the grounding-breaking innovation of the '540 patent, and the full opportunity to capitalize on its window of opportunity to sell the MaterniT21 test before the patent expires or new technology renders it obsolete.

57. Another imperative for preventing Aria from entering the market during the pendency of this litigation is the likelihood that Aria would not be able to satisfy an award of damages to Sequenom for Aria's infringement. Aria is a small, venture-backed private company

that appears by its public statements and web site to have no product or service other than its infringing prenatal fetal aneuploidy test. Aria publicly announced in its press release of January 9, 2012, that it secured over $50 million in funding from several venture capital firms. A true and correct copy of Aria's press release is attached to this declaration as Exhibit 13. It is likely that this funding will be spent on a clinical study that Aria announced it has launched in its press release dated January 12, 2012, a true and correct copy of which is attached hereto as Exhibit 14. William Blair, in its January 16, 2102 report, stated that Aria "completed a $52.7 million series C round of financing, which we believe will in large part be used for a massive 25,000-women clinical study that the company announced it would undertake." *See* Exhibit 9 at 3. Later in this same report, William Blair states: "We note that this will be a lengthy trial given the size of the study and the fact that an additional seven months will be needed following the last enrollee so that the pregnancy can be carried to term. When adding in the time to collect and analyze the data, we expect that this could be a 20-month-plus endeavor." *Id*.

58. It is my understanding that when venture-backed companies fail and become insolvent, there typically is no legal recourse against the venture capital firms. Because Aria is a small, venture-backed company, Sequenom is concerned that Aria may not be in a position to fully satisfy a damages award upon a final judgment that its Harmony Prenatal Test infringes the '540 patent. Sequenom's diminished chances of recovering from Aria any, much less all, of a damages award for Aria's infringement constitutes real and irreparable harm.

59. Sequenom also will be irreparably harmed by any market confusion that results from Aria's entry into the marketplace. If Aria puts an inferior service of the market, or if it markets its service "off label" for uses that are not supported by clinical data – by, for instance, marketing its Harmony Prenatal Test to women with low risk of fetal aneuploidy pregnancies – Aria will poison the market and irreparably harm Sequenom's opportunity to create and exploit a sustainable market. The market for non-invasive tests for fetal aneuploidies is a new market that is aimed at supplementing and ultimately supplanting the current standard of care, which calls for invasive tests such as amniocentesis and CVS. It is important that non-invasive tests for fetal aneuploidies be validated by further clinical studies before a broad release to the market.

60. Sequenom is a public company and its investors have made a substantial investment in the company on the expectation that Sequenom would be afforded exclusive rights to use the innovative technology embodied by the '540 patent for a non-invasive prenatal test for fetal aneuploidies. In public offerings since May 2010, investors have purchased shares of Sequenom stock that have resulted in net proceeds to Sequenom of over $197 million. Sequenom and its shareholders will be substantially and irreparably harmed if Aria is allowed to piggy-back off of Sequenom's patented technology.

61. As described earlier in this declaration, Sequenom has used and will use a large portion of those funds to develop, launch, and rollout the MaterniT21 test. Sequenom has expanded its marketing and operating capacity, including expansion of sales force, laboratory, and information technology infrastructures, with the expectation that Sequenom would enjoy the full measure of its exclusive rights under the '540 patent. If Sequenom is denied this right and Aria is allowed to enter the market during the pendency of this lawsuit, then Sequenom's deliberate planning will be adversely affected, and the impacts will be immediate because the MaterniT21 test is early in its growth phase. Sequenom's loss of revenue resulting from Aria's infringement will deprive Sequenom of the funds that could otherwise use to sustain an upward trajectory of the rollout of the MaterniT21 test and the expansion of operational capacity geared to match the expected growth of the market. This loss of revenue and market share likely will force Sequenom to reduce its operating expenses, including reducing the number of sales force personnel and halting facilities build-outs and improvements.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that this declaration was executed on March 8, 2012, in Grand Rapids, Michigan.

/s/ William Welch
William Welch

I Michael Malecek, the ECF filer of this document hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/s/) within this efiled document.